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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,894	06/01/2006	Katri Keski-Nisula	PLA078-820714	7027

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WOLF BLOCK SCHORR AND SOLIS-COHEN LLP
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NEW YORK, NY 10177

EXAMINER

PATEL, YOGESH P

ART UNIT	PAPER NUMBER
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3732

NOTIFICATION DATE	DELIVERY MODE
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02/21/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO@WOLFBLOCK.COM

Office Action Summary	Application No. 10/563,894	Applicant(s) KESKI-NISULA ET AL.	
	Examiner YOGESH P. PATEL	Art Unit 4111	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 24 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 January 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/09/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-23, drawn to an odontological device.

Group II, claim(s) 24-25, drawn to a method in orthodontics for selecting an occlusion guidance appliance device.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Independent claim 1 of Group I includes special technical features that requires (a) a generally U-shaped arch made of flexible material and that has a lower surface on the lower jaw side and an upper surface on the upper jaw side; (b) an isthmus including blanks and (c) the lower jaw side surface having a lower wing which requires different technical features from Group II, which requires (a) measuring the length of the upper jaw side dental arch from an individual's teeth and (b) choosing, based on the measurement without taking separately into consideration the development phase of the teeth of independent claim 24 in group II and vice versa. Therefore, a holding that these two groups do not have a single inventive concept.

3. During a telephone conversation with Dippert William on 12/17/2007 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-23. Affirmation of this election must be made by applicant in replying to this Office action. Claims 24-25 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result**

in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23, 25-27 of U.S. Application No. 10/563,886 in view of US Patent No. 4,784,605. Independent claim 1 of 10/563,894 differs in that of independent claim 1 of 10/563,886 which requires a generally U-shaped arch made of flexible material of an odontological device for guiding the occlusion of an individual, which is taught by the Patent No. 4,784,605 to provide a soft cushioning engagement with the posterior teeth as they contact the isthmus in the posterior region of the appliance to depress the posterior teeth (col. 3, lines 13-16) and therefore the claim is obvious. See the claims comparison table below:

10/563894	10/563886
Claim limitations	Claim limitations
Claims 1 and 2: a generally U-shaped arch that has a lower surface on the lower jaw side and an upper surface on the upper jaw side	Claim 1: a generally U-shaped arch that has a lower surface on the lower jaw side and an upper surface on the upper jaw side
the bottoms of the concaves forming an isthmus which separates the concaves from one another. Although, '894 is silent about the walls of the concaves formed by outer walls on the labial or buccal side, and of inner walls arranged on opposite sides of the concaves on the lingual side of the tongue, it is noted that the presence of the upper surface, the isthmus and the generally U-shaped arch requires outer walls on the labial or buccal side, and inner walls arranged on opposite sides of the concaves on the lingual side of the tongue as recited in '886.	the bottoms of the concaves forming an isthmus separating the concaves and the walls of the concaves are formed by the outer walls on the labial or buccal side, and of inner walls arranged on the opposite sides of the concaves on the lingual side of the tongue,
the isthmus includes blanks, as taken to be recesses for individual teeth	the isthmus between the concaves having recesses for individual teeth
the recesses contain uniform compartment that begin from the second premolar and continue towards the molars at least partly to the area where the second permanent molar will erupt	the recesses consist of uniform compartments, which start from second premolar and continue toward the molars at least partially to the area where the second permanent molar will erupt.
Claim 3: the side walls of the uniform compartments are formed by outer and inner walls, which have essentially straight walls.	Claim 2: side walls of the uniform compartments are formed by outer and correspondingly inner walls, which have essentially straight walls.

Claims 4-23: same structural limitations as claims 3-10 of '886.	Claims 3-23: same structural limitations as claims 4-10 of '894.
Claims 11-23 are identical to claims 11-23 of '886.	Claims 11-23 are identical to claims 11-23 of '894.
Claims 24-25 are not patentably distinct from claims 25-27 of '886.	Claims 25-27 are not patentably distinct from claims 24-25 of '894.

Drawings

7. The drawings are objected to because in figure 1, element 14 is not properly pointing at the intended structure. Appropriate correction is required.
8. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4). Applicant has used inconsistent reference numerals throughout the specification for claimed elements and are too numerous to list. For example reference character "5a" has been used to designate both side wall and outer wall. The objection to the drawings will not be held in abeyance.
9. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

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Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

10. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. **It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited.** The form and legal phraseology often used in patent claims, such as "means" and "the," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected because it exceeds 150 words limit. Appropriate correction is required.

11. The disclosure is objected to because of the following informalities: Applicant has used the claims in the specification to describe the invention. For example, on page 1, "an odontological device according to the preamble of Claim 1 for guiding the occlusion of an individual" should be avoided and proper description of the invention is requested.

Applicant has repeated such language throughout the specification of the disclosure. Appropriate correction is required.

12. The specification is objected to for failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). The claims are replete with terms that lack antecedent basis in the specification. Appropriate

correction is required. Applicant is required to use consistent language for all claimed features throughout the specification to clarify the invention. Applicant has used inconsistent language throughout the specification for claimed elements to numerous to list. For example, consistent terminology has not been used for the side walls, the outer walls, the inner walls and the front walls (e.g. 4a, 5a, 4b, 5b) of the dental appliance.

13. The cross-reference(s) to related applications, if any, should be in the first sentence of the specification. An appropriate correction is required.

Claim Rejections - 35 USC § 112

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner further notes that the claims are replete with elements that lack the antecedent basis. For example, Claim 10 recites the limitation "wherein the walls of the concaves are formed by the outer walls on the labial side." There is insufficient antecedent basis for this limitation in the claim. The claims as presently

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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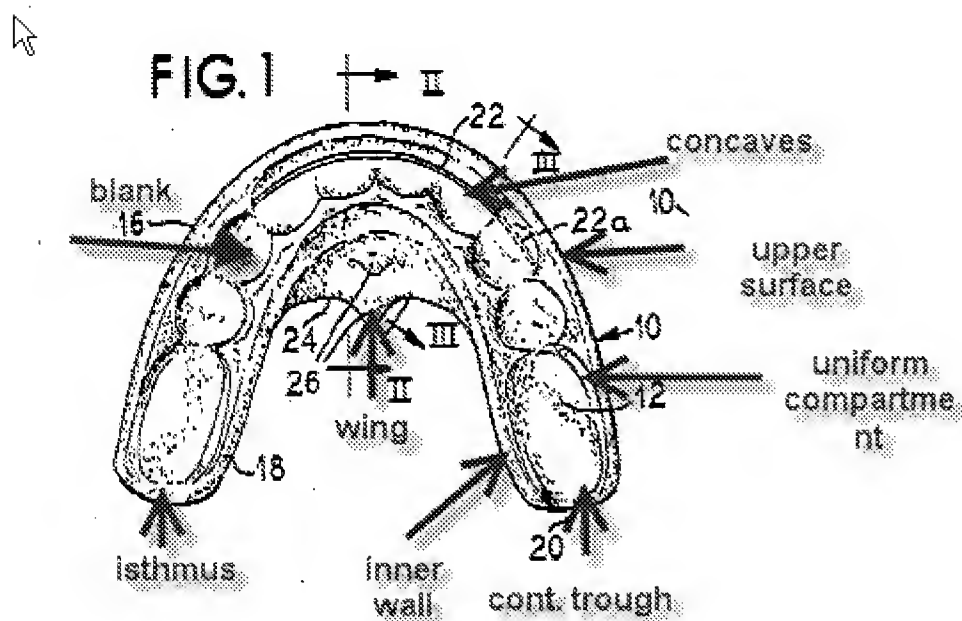
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

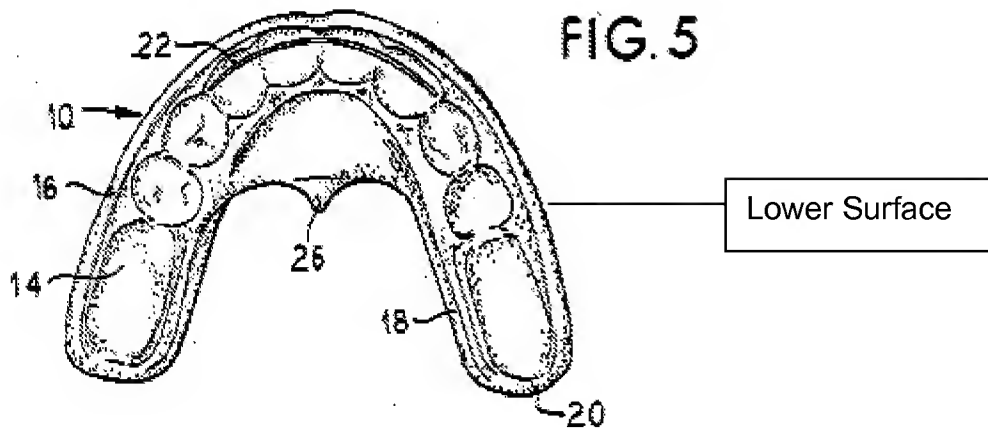
17. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Bergersen (Pat. 4,784,605).

Regarding claim 1 Bergersen discloses an orthodontic device for guiding the occlusion of an individual, the device including a generally U-shaped arch made of flexible material (col. 3, lines 13-16) and that has a lower surface on the lower jaw side and an upper surface on the upper jaw side, and in both of which there are concaves for receiving the individual's teeth (col. 2, lines 35-40), the bottoms of the concaves forming an isthmus which separates the concaves from one another, wherein the isthmus includes blanks intended for individual teeth and uniform, continuous recesses (e.g. trough) for at least two teeth to guide the teeth in the required direction, and the lower jaw side surface has a lower wing constricting the tongue at least sideways, and it has been shaped to further placement of the device in the individual's mouth (see the provided figure). Regarding claim 2 Bergersen discloses the recesses (e.g. trough) contain uniform compartments that begin from the second premolar and continue towards the molars at least partly to the area where the second permanent molar will erupt (see the provided figure). Regarding claim 3 Bergersen discloses the side walls of the uniform compartments are formed by outer and inner walls, respectively, which have essentially straight walls (see the provided figure). Regarding claim 4 Bergersen discloses the compartments are shaped like continuous troughs, and the troughs are open from the molar side end (see the provided figure). Regarding claim 5 Bergersen discloses the recesses contain uniform recesses (compartment) limited to the area of

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the front teeth, and the surface walls of the recesses are essentially smooth. Regarding claim 6 Bergersen discloses the concaves have their own blanks for canine teeth and the first premolars (see the figure).





Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claim 7-9 and 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergersen'605 as applied to claim 1 above, and further in view of Bergersen (Pat. 5,645,420).

Regarding claim 7-9, Bergersen'605 discloses all elements of the claimed invention except for a thickness of the isthmus.

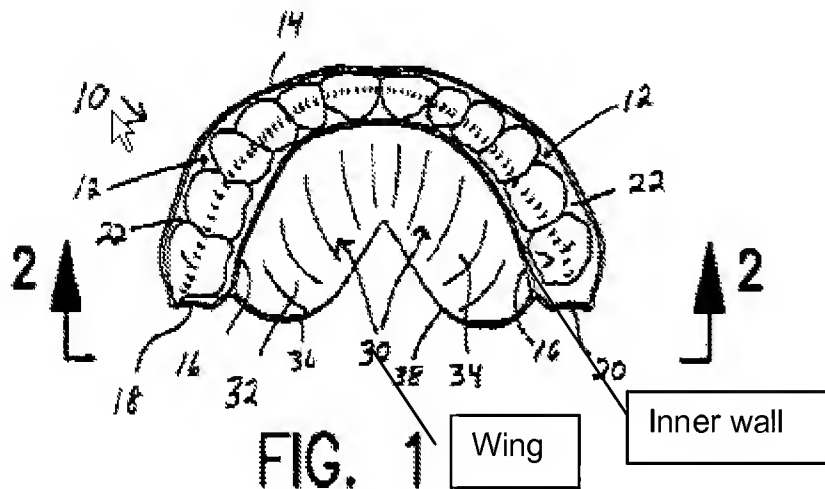
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Bergersen '420 teaches the variation of the isthmus thickness for the correction of the overbite can be accomplished either by reducing the thickness in the area of the posterior teeth or increasing the thickness in the area of the anterior teeth (col. 6-7). Similarly, by increasing the thickness of the isthmus in the posterior region relative to the anterior region, an open bite can be corrected. The variation in thickness of the isthmus occurs in step because the thickness is different in anterior and posterior portions. It would have been obvious to a person of ordinary skill in the art at the time of the invention was made to have provided a varying thickness of the isthmus of the device as taught by Bergersen'420 to the orthodontic device of Bergersen to correct open bite/overbite problems (col. 6, lines 49-67 and col. 7, lines 19-42).

Regarding claims 18-23, Bergersen'605 discloses all elements of the claimed invention except for the measurements of the appliance(s).

Bergersen'420 teaches a series of differently sized orthodontic appliances which are each preformed to be generally in U-shapes (claims 32-36). Further, the dental structure of users (e.g. dentition) varies in sizes depending on particular users' age. For example, if the user is 5 years old, then the length of the compartment would be lesser than the compartment length for user that is older than specified age and vise versa. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention was made to have provided the appliance in variety of sizes (e.g. as claimed) as taught by Bergersen'420 to the dental appliance of Bergersen'605 so that large group of users may benefit from correcting open-bite tendencies and tongue thrust problems using the appliance.

20. Claims 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergersen'605 as applied to claim 1 above, and further in view of DeLuke (Pat. 6,837,246).



Bergersen'605 discloses all elements of the claimed invention except for the lower wing extending lower than the corresponding outer wall, reaching the immediate proximity of the mouth cavity, shape of lower arch, reducing the at point of the ligament of the tongue and outer wall on the upper jaw side surface partially continued upwards. Regarding claim 10 DeLuke teaches the walls of the concaves are formed by the outer walls on the labial side or on the buccal side, respectively, and by the inner walls on the opposite sides of the concaves on the lingual side, the inner wall on the lower jaw side surface being continued so that it is at least essentially aligned downwards to the wall surface in such a way that it extends lower than the corresponding outer wall to form the lower wing (fig. 1-3). Regarding claim 11 DeLuke teaches the wing has been arranged

so as to reach the immediate proximity of the base of the mouth cavity (fig. 1).

Regarding claim 12 DeLuke teaches shape of the lower wing, particularly in the molar area, follows essentially the shape of the lower side jaw arch (fig. 1). Regarding claims 13 and 14 DeLuke teaches the downwards dimension of the wing has been reduced at the point of the ligament of the tongue (fig. 1). DeLuke does not explicitly teaches lower wing extends approximately at the point of the first molar to a distance of 14 mm as a maximum of the down side surface of the isthmus, in which case the distance is approximately 3 to 6 mm smaller in the area of the ligament of the tongue, however the figures clearly shows that the wing is reduced at the point of the ligament of tongue. If the wing is not reduced at the point of the ligament, then it would be difficult to maintain the appliance in the mouth. Regarding claims 15-17 DeLuke teaches the outer wall 14 on the upper jaw side surface has been continued upwards to the wall surface in such a way that it extends above the gum line, and in relevant range because if measured from the isthmus to the top surface of the appliance is too large, then the appliance would be inappropriate for the user because there would no passage for saliva to exit the appliance. Further the size of the appliances corresponds to increasing the width and the height of the dental arch to make appropriate for young children thru adults (end of col. 2 to col. 3), thus outer wall is also increased in terms of height for adult users.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention was made to have provided the wing of DeLuke to the dental appliance of Bergersen'605 for enhancing retention of the appliance into the user's mouth and to

encourage users to breath through the nose, and which can serve as a diagnostic aid or test device to access a patient's problems (summary of the invention).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YOGESH P. PATEL whose telephone number is (571)270-3646. The examiner can normally be reached on Monday to Thursday about 8 AM- 5 PM Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sam Yao can be reached on 5712721224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

YP

01/04/2007

/Sam Chuan C. Yao/

Supervisory Patent Examiner, Art Unit 4111